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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,300	01/22/2002	Takeshi Imanishi	01834CIP/HG	5360

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EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,300	IMANISHI ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 23-28, drawn to compounds of formula 1 where B is a purine base, classified in class 536, subclass 27.1.

II. Claims 1-10 and 23-28, drawn to compounds of formula 1 where B is a pyrimidine base, classified in class 536, subclass 28.1.

III. Claims 11-13 and 19-22, drawn to oligonucleotides comprising the compound of formula 1a, classified in class 536, subclass 23.1.

IV. Claim 14, drawn to a composition comprising the oligonucleotide of group II, classified in class 514, subclass 44.

V. Claims 15-18, drawn to methods of treating or preventing diseases using the oligonucleotide of group II, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are independent and distinct from each other as they are drawn to compounds which have divergent moieties in the B position. Groups I and II are directed to or involve the use of compounds which have B-groups that are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects, and reactive conditions. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e., they are patentable over each other. Chemical structures which are similar are presumed to function

similarly, while chemical structures which are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of ***Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)***, and ***In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984)***, chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Inventions I and III are unrelated. The inventions of group I and III are drawn to patentably distinct products wherein group I is drawn to a compound and group III is drawn to an oligonucleotide. A reference anticipating or rendering obvious the compounds of group I would not necessarily anticipate or render obvious the oligonucleotides of group III, and further search and consideration would be required.

Inventions I and IV are unrelated. Group I is drawn to a compound of formula I and group IV is drawn to a composition comprising an oligonucleotide. A reference anticipating or rendering obvious the compounds of group I would not necessarily anticipate or render obvious the compositions comprising the oligonucleotides of group IV, and further search and consideration would be required.

Inventions I and V are unrelated. Group I is drawn to a compound of formula I and group V is drawn to methods of treating diseases using compositions comprising an oligonucleotide of Group III. A reference anticipating or rendering obvious the compounds of group I would not

necessarily anticipate or render obvious the methods of using compositions comprising the oligonucleotides as set forth in group V, and further search and consideration would be required.

Inventions II and III are unrelated. The inventions of group II and III are drawn to patentably distinct products wherein group II is drawn to a compound and group III is drawn to an oligonucleotide. A reference anticipating or rendering obvious the compounds of group II would not necessarily anticipate or render obvious the oligonucleotides of group III, and further search and consideration would be required.

Inventions II and IV are unrelated. Group II is drawn to a compound of formula I and group IV is drawn to a composition comprising an oligonucleotide. A reference anticipating or rendering obvious the compounds of group II would not necessarily anticipate or render obvious the compositions comprising the oligonucleotides of group IV, and further search and consideration would be required.

Inventions II and V are unrelated. Group II is drawn to a compound of formula I and group V is drawn to methods of treating diseases using compositions comprising an oligonucleotide of Group III. A reference anticipating or rendering obvious the compounds of group II would not necessarily anticipate or render obvious the methods of using compositions comprising the oligonucleotides as set forth in group V, and further search and consideration would be required.

Inventions III and IV are patentably distinct. The inventions of groups III and IV are drawn to patentably distinct products wherein group III is drawn to a compound and group IV is drawn to a composition comprising an oligonucleotide. A reference anticipating or rendering

obvious the compounds of group III would not necessarily anticipate or render obvious the compositions of group IV, and further search and consideration would be required.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process can be practiced with another materially different product, such as with the product of group IV.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process can be practiced with another materially different product, such as with the product of group III.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Due to the complexity of the restriction requirement, no telephone call was made to applicants to request an oral election to the above restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Claims 1-28 are generic to a plurality of disclosed patentably distinct species comprising a plethora of divergent compounds represented by the Markush group of formula 1 and the enormous quantities of nucleotides which may contain the same. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By a single species it is meant the identity of a single compound, and if the claimed methods are elected, the identity of the actual disease state treated. The compound may be named in any of four ways: 1) according to IUPAC standard, 2) by a pictorial representation of the compound, 3) by setting forth the specific chemical group that each variable of the Markush group represents, or 4) by naming a claim or an example which itself sets forth a single compound.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
April 11, 2006

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623

4/12/06